



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
William A. Hinton State Laboratory Institute
305 South Street, Jamaica Plain, MA 02130

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May 3, 2012

Gerard T. Leone, Jr
District Attorney, Middlesex
County District Attorney's Office
15 Commonwealth Avenue
Woburn, MA 01801

Dear District Attorney Leone,

I am writing to inform you that we investigated a breach of protocol with respect to ninety drug samples tested at the William A. Hinton State Laboratory Institute in June, 2011. At the conclusion of our investigation, there was no evidence that this breach in protocol had any impact of the integrity of the samples or the accuracy of the sample analysis. Additionally, measures were immediately taken to ensure proper compliance with protocol procedures. The samples identified were received exclusively from Norfolk County; no samples from any other county were involved. Accordingly, only the Norfolk County District Attorney was notified. This letter provides each County's District Attorneys Office with the information that was made available to Norfolk.

The Lab's protocols for handling evidence samples require that all samples received for testing be given a unique sample identifier called an evidence control number. The Lab uses the control number to track the samples as they undergo the testing process. The control numbers are initially entered into a computer tracking system and log book when first received by the Lab, and a card (control card) containing the control number is attached to the sample. When the samples are transferred out of the evidence office for testing, they are manually recorded in the office log book (log book) and computer tracking system. An evidence officer is required to record his/her initials, the date of the transfer and the initials of the chemist accepting receipt of the sample(s) in the log book. The chemist receiving the sample is required in the presence of the evidence officer to record his/her initials signifying his/her receipt. The chemist also initials the control card after completing the testing process.

These protocols have been consistently followed with regard to the drug samples, ensuring that the integrity of the samples is protected and providing drug analytical results that are expertly prepared and accurate.

Because of the mechanisms in place to identify problems, Laboratory personnel quickly became aware of a potential breach in its recording protocols on June 16, 2011 when an evidence officer noted that the information displayed on the computer for a case did not show the sample(s) for that case as having been assigned to the chemist identified on the control card. This process was repeated for other samples in the same batch with the same results. Further investigation revealed no entries in the log book recording a transfer of these samples from the evidence office to the chemist for testing on June 14, 2011.

The evidence officer immediately contacted her supervisor to alert her of the irregularity. The supervisor, in turn, on June 20th brought this to the attention of her supervisor, the Laboratory's Director of the Division of Analytic Chemistry and, in addition, to my attention and the attention of the Supervising Chemist for the Analysis Section. On the same day, June 20th, they all examined the log book and confirmed that there had been no recording of a transfer of these samples from the evidence office to the chemist for testing on June 14th. On June 21st, when the log book was reexamined, entries did appear showing a transfer of the samples from the evidence office to the chemist. It appeared that these entries were made by the chemist after June 14th.

The chemist involved in this case has been employed by the Department for eight years. Prior to this incident, she had no personnel issues and was well respected for the accuracy of her work and her dedication to the Laboratory's mission. In review of the incident, the managers at the Laboratory did not believe there was any reason to believe that the integrity of the samples had been affected by the breach in protocol or the late entries in the log book. However, the chemist was removed from all responsibilities involving laboratory analysis as of June 21, 2011.

The Commissioner's office first became aware of this incident on December 1. The Laboratory managers had not reported this incident to the DPH Central Office because they did not appreciate its potential legal significance and because of their opinion that the integrity of the test results had not been affected. The Central Office conducted its own investigation of the incident and confirmed that there was no evidence to suggest that the integrity of the results was impacted by the documentation issue with the log book. The Department's Human Resources Division is reviewing what appropriate disciplinary actions should be taken.

Within the single batch that shared this documentation breach, there were a total of 90 evidence samples, all of which were from Norfolk County.

The Department has taken a number of steps to minimize any reoccurrence of this nature. The Laboratory revised and strengthened its protocols for handling test samples. The new protocols include more secure, redundant mechanisms for tracking and transferring samples, and limit direct access to the samples to the evidence officers.

Sincerely,

Linda Han, MD, MPH
Director, Bureau of Laboratory Sciences
William A. Hinton State Laboratory Institute